Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0996062	06/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Regional Cancer Care Associates	18 Newark Pompton Turnpike, Riverdale, NJ	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to retain all QC records for tests performed on the Horiba ABX Pentra 60C+ from January 2020 to the date of survey. The finding includes: 1. All Hematology QC that was repeated due to a failed QC run were not retained. 2. The OM confirmed on 6/1/2022 at 11:00 am that the all QC records were not retained.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM), the laboratory failed to review and evaluate results when they received an unacceptable score in Hematology tests performed with the American Proficiency Institute (API) for the second and third event in the calendar year 2021. The findings include: 1. The laboratory received an "unacceptable" Grade for Blood Cell Identification sample BCI-15 event 3, 2021 2. The laboratory received an "Not Graded 2" Grade for Blood Cell Identification sample BCI-07 event 2, 2021 3. There was no documented evidence that the laboratory investigated the failures. 4.

	The OM confirmed on 6/1/2022 at 10:45 am that the laboratory did not review and document an evaluation of unacceptable PT results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Operators Manual (OM) and interview with the Office Manager (OM), the laboratory failed to follow their procedure for "Error Flags" from 1/10/22 to the date of survey. The finding include: 1. OM page 113 "6. Results Interpretation", "6.1 General Alarms" "6.1.1. Parameter Reject" states as follows: a) "6.1.1. Parameter Reject, A Parameter reject is show by "*" and indicates that the result is not coherent. The sample has to be checked. A rejected result cannot be validated." b) Sample ID 508734, 151393,149936, White Blood Cell Count (WBC) were flagged with an "*" on 5/25/2022 and were not checked and rerun . c) Sample ID 309534, 119295, WBC were flagged with an "*" on 5/31/2022 and were not checked and rerun . 2. OM page 114 "6. Results Interpretation", "6.1 General Alarms", "6.1.2 Suspicion" states as follows: a) "LMNE Suspicion", "Condition: "!" on WBC", "Action: The result is presumed erroneous, it must be checked with a rerun sample or with a reference method if the second result is still alarmed." b) Sample ID 102972, 108148, 264660, 510529 were flagged with an "!" on 5/25/2022 and were not checked and rerun. c) Sample ID 99042, 103075, 118979, 510529, were flagged with an "!" on 5/27/2022 and were not checked and rerun. d) Sample ID 509101, 480693, 102344, 97417, 506537, 510529, were flagged with an "!" on 5/31/2022 and were not checked and rerun. 3. The OM confirmed on 6/1/2022 at 11:21 am the policy "6. Results Interpretation" were not being followed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Calibration (C) records, User Manual (UM) and interview with the Office Manager (OM), the laboratory failed to perform, document and meet acceptable limits for all Calibration results and procedures at least once every six months for Hematology Tests performed on the Horiba Pentra 60c+ analyzer

	in the calendar year 2021. The findings include: 1. A review of C records revealed that the laboratory failed to perform and document "repeatability" a) The UM states in the "Preparation for Calibration" procedure to "perform a repeatability study by running one normal patient sample ten times mixing well before each run. Ensure repeatability is acceptable by making certain the variation coefficients are displayed in black font" 2. The laboratory last performed C 9/2/2021, but there was no documented evidence CV was performed after that date. 3. C failed meet acceptable limits for White Blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin (HGB), and Platelets (PLT) on 7/17/2020. 4. C Failed to meet acceptable limits for WBC, RBC, and PLT on 1/29/2021 5. The OM confirmed on 6/1/2022 at 11:32 am that the laboratory failed to perform, document and meet acceptable limits for C once every six months.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Office Manager (OM) and Testing Personal (TP), the laboratory failed to document all corrective action when High, Normal, or Low controls were out of range and had to be rerun for hematology tests performed on the Horiba ABX Pentra 60C+ analyzer from January 2020 to the date of survey. The findings include: 1. There was no corrective action log for QC. 2. The TP stated "They do not keep work records or documentation for failed QC runs", and "do not document corrective action when QC is out of range and has to be rerun". 3. The OM confirmed on 6/1/2022 at 11:00 am that the laboratory failed to document all corrective action.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Horiba ABX Pentra 60C+ analyzer were adequate from January 2020 to the date of survey. The findings include: 1. The LD did not review and sign the PS results. 2. There was no raw data to support the PS

	results. 3. The OM confirmed on 6/1/21 at 10:35 am that PS records were not adequate.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the surveyor review of the User Manual (UM) Quality Assessment Procedure (QAP) and interview with the Officer manager (OM), the Laboratory Director failed to ensure that the QA program was maintained from July 2020 to the date of survey. The finding includes: 1. The UM QAP stated as follows: a. "4.5 Red Cell Distribution Width (RDW)", "The RDW cannot be calibrated during the automatic calibration. It has to be manually adjusted." b. "In order to get the appropriate RDW coefficient, use the formula: New RDW coefficient = (Expected RDW* / Current RDW mean**) X Current RDW coefficient" 2. There was no documented evidence that the aforementioned QA was performed. 3. The TP #2 listed on CMS form 209 confirmed on 12/17/21 at 10:20 am that the laboratory did not maintain the QA program.